

**PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Marina KONOPLEVA et al.

Serial No.: 09/998,009

Filed: November 28, 2001

For: CDDO-COMPOUNDS AND  
COMBINATION THERAPIES THEREOF

Group Art Unit: 1614

Examiner: ANDERSON, James

Atty. Dkt. No.: UTSC:652US

Confirmation No.: 7245

**CERTIFICATE OF ELECTRONIC TRANSMISSION**

I hereby certify that this correspondence is being electronically filed with the United States Patent and Trademark Office via EFS-Web on the date below:

August 14, 2007

Date

Steven L. Highlander

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

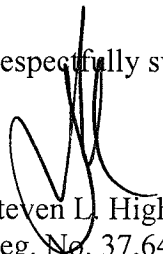
This application may be related by inventorship or subject matter to co-pending U.S. application number 11/121,316, filed May 3, 2005.

Applicants certify, in accordance with 37 C.F.R. § 1.97(e)(2), that no item of information contained in this Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in this Supplemental Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Supplemental Information Disclosure Statement.

The required fee in the amount of \$180.00 in connection with the filing of this paper are being charged to a credit card through EFS-Web concurrently with this submission. The Commissioner is hereby authorized to deduct any underpayment of fees or any additional fees required under 37 C.F.R. §§ 1.16 to 1.21 in connection with the filing of this paper from Fulbright & Jaworski Deposit Account No.: 50-1212/UTSC:652US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,

  
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Date: August 14, 2007

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### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	2002/0042535	04/11/02	Gribble <i>et al.</i>	558	429	08/09/01
	A2	4,395,423	07/26/83	Neumann	424	304	12/06/79
	A3	5,064,823	11/12/91	Lee <i>et al.</i>	514	198	05/01/90
	A4	5,603,958	02/18/97	Morein <i>et al.</i>	424	489	05/31/95
	A5	6,326,507	12/04/01	Gribble <i>et al.</i>	558	415	06/17/99
	A6	6,485,756	11/26/02	Aust <i>et al.</i>	424	725	04/06/00

### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Language

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	C33	Ambs <i>et al.</i> , "p53 and vascular endothelial growth factor regulate tumor growth of NOS2-expressing human carcinoma cells," <i>Nat. Med.</i> , 4(12):1371-1376, 1998.
	C34	Andreeff <i>et al.</i> , "PPARgamma nuclear receptor as a novel molecular target in leukemias," <i>2002 Keystone Symposia</i> , Abstract No. 501, 2002.
	C35	Bliard <i>et al.</i> , "Glycosylation of acids under phase transfer conditions. Partial synthesis of saponins," <i>Tetrahedron Lett.</i> , 35:6107-6108, 1994.
	C36	Bogdan <i>et al.</i> , "Contrasting mechanisms for suppression of macrophage cytokine release by transforming growth factor-beta and interleukin-10," <i>J. Biol. Chem.</i> , 267:23301-23308, 1992.
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	C38	Boolbol <i>et al.</i> , "Cyclooxygenase-2 overexpression and tumor formation are blocked by sulindac in a murine model of familial adenomatous polyposis," <i>Cancer Res.</i> , 56(11):2556-2560, 1996.
	C39	Bore <i>et al.</i> , "The anti-inflammatory triterpenoid methyl 2-cyano-3, 12-dioxoolean 1,9(11)-dien-28-oate methanol solvate hydrate," <i>Acta Crystallorg C.</i> , 58(Pt 3):o199-o200, 2002.
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	C50	Elsawa <i>et al.</i> , "Preferential Inhibition of Malignant Cell Growth by CDDO in Waldenstrom Macroglobulinemia," <i>Blood</i> , 108(11):2528, 2006.
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	C63	Ikeda <i>et al.</i> , "The novel triterpenoid CDDO and its derivatives induce apoptosis by disruption of intracellular redox balance," <i>Cancer Res.</i> , 63:5551-5558, 2003.
	C64	Johansen <i>et al.</i> , "Pharmacology and preclinical pharmacokinetics of the triterpenoid CDDO methyl ester," <i>Proc. Amer. Assoc. Cancer Res.</i> , 44:1728, 2003.
	C65	Johnson <i>et al.</i> , "A plan for distinguishing between some five- and six-membered ring ketones," <i>J. Am Chem. Soc.</i> , 67:1745-1754, 1945.
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	C74	Konopleva <i>et al.</i> , "PPARgamma Nuclear Receptor as a Novel Molecular Target in Leukemia Therapy," <i>Proc. Amer. Assoc. Cancer Res.</i> , 43:4730, 2002.
	C75	Konopleva <i>et al.</i> , "PPARgamma Nuclear Receptor as a Novel Therapeutic Target in AML," <i>Proc. Amer. Assoc. Cancer Res.</i> , 42:4458, 2001.
	C76	Konopleva <i>et al.</i> , "Suppression of ERK Activation is Required for Triterpenoid Methyl-CDDO-Induced Apoptosis in AML," <i>Blood</i> , 102(11):1404, 2003.
	C77	Konopleva <i>et al.</i> , "Synthetic triterpenoid 2-cyano-3,12-dioxooleana-1,9-dien-28-oic acid induces growth arrest in HER2-overexpressing breast cancer cells," <i>Mol. Cancer Ther.</i> , 5:317-328, 2006.
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	C82	Kress <i>et al.</i> , "Triterpenoids Display Single Agent Activity in a Mouse Model of CLL/SBL," <i>Blood</i> , 108(11):2530, 2006.
	C83	Kress <i>et al.</i> , "Triterpenoids Display Single Agent Anti-tumor Activity in a Transgenic Mouse Model of Chronic Lymphocytic Leukemia and Small B Cell Lymphoma," <i>PLoS ONE</i> , 6(e559):1-11, 2007.
	C84	Kurinna <i>et al.</i> , "The novel triterpenoid CDDO-Me promotes apoptosis in Gleevec-resistant chronic myeloid leukemia cells by caspase-independent mechanisms," <i>Proc. Amer. Assoc. Cancer Res.</i> , 46:2240, 2005.

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	C86	Lemieux, "Acylglycosyl Halides. [55] tetra-O-acetyl- $\alpha$ -D-glucopyranosyl bromide," <i>Methods Carbohydr. Chem.</i> , 2:221-222, 1963.
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	C89	Marnett, "Aspirin and the potential role of prostaglandins in colon cancer," <i>Cancer Res.</i> , 52(20):5575-5589, 1992.
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	C98	Ono <i>et al.</i> , "A convenient procedure for esterification of carboxylic acids," <i>Bull. Chem. Soc. Jpn.</i> , 51:2401-2404, 1978.
	C99	Oshima <i>et al.</i> , "Suppression of intestinal polyposis in Apc <sup>A716</sup> knockout mice by inhibition of cyclooxygenase 2 (COX-2)," <i>Cell</i> , 87:803-809, 1996.
	C100	Pedersen <i>et al.</i> , "The triterpenoid CDDO induces apoptosis in refractory CLL B cells," <i>Blood</i> , 100:2965-2972, 2002.
	C101	Picard <i>et al.</i> , "The triterpene resinols and related acids, part VI," <i>J. Chem. Soc.</i> , 1045-108, 1939.
	C102	Place <i>et al.</i> , "The novel synthetic triterpenoid, CDDO-imidazolide, inhibits inflammatory response and tumor growth in vivo," <i>Clin. Cancer Res.</i> , 9:2798-2806, 2003.
	C103	Prescott and White, "Self-promotion? Intimate connections between APC and prostaglandin H synthase-2," <i>Cell</i> , 87:783-786, 1996.
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Form PTO-1449 (modified)		Atty. Docket No.: UTSC:652US	Serial No.: 09/998,009
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant: Marina Konopleva	
		Filing Date: November 28, 2001	Group: 1614
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1-10</i>	

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Exam. Init.	Ref. Des.	Citation
	C110	Samudio <i>et al.</i> , "A novel mechanism of action of methyl-2-cyano-3,12 dioxoolean-1,9 diene-28-oate (CDDO-Me): Direct permeabilization of the inner mitochondrial membrane to inhibit electron transport and induce apoptosis," <i>Proc. Am. Assoc. Cancer Res.</i> , 47: 4693, 2006.
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